

# ASTA 2020 Regulatory Workshop

*web series*

Welcome!





# Prop 65 and Spices

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# The Basics

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- Proposition 65 is a "right to know" law based on the idea that consumers should be warned before being exposed to carcinogens or reproductive toxicants
- Prop 65 requires businesses with 10 or more employees to provide “clear and reasonable warnings” for “exposures” above regulatory safe harbor levels to substances that are listed by California.
- Approximately 900 listed substances
- The warning requirement applies to all companies in the chain of distribution (manufacturers, packagers, distributors, and retailers)
- Manufacturers and/or packagers typically bear the ultimate burden on compliance

# Warnings

- Old safe harbor warning

**WARNING:** This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

- New safe harbor warning



**WARNING:** This product can expose you to Di(2-ethylhexyl)phthalate (DEHP), a chemical known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov/](http://www.P65Warnings.ca.gov/)

# Warnings Cont.

- Foods Warning:

**WARNING:** Consuming this product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov/food](http://www.P65Warnings.ca.gov/food).

- Short Form:

**WARNING:** Cancer and Reproductive Harm -  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

- Online warning requirement

- Best option for spice companies?

- Likely foods warning referencing one listed substance that covers both end points (cancer and reproductive toxicity)

# Enforcement

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- California AG's Office, a district attorney, a city attorney (for cities whose population exceeds 750,000), a private entity, or a citizen can enforce Proposition 65
- Public enforcement is very rare
- Private enforcer must issue 60-Day Notice of Violation to alleged violator and public enforcers before proceeding with a lawsuit
- Over 2,500 Notices of Violation last year
- Penalties for violating Proposition 65 can be as high as \$2,500 per violation, plus plaintiff attorneys' fees

# Exposures

- Prop 65 regulates EXPOSURES caused by foreseeable use of products, not the concentration of listed substances in a product
- How is exposure calculated?
  - Average dose X chemical concentration = exposure per dose/serving
- Average dose?
  - For foods with an on-label serving recommendation, it's normally a pretty easy calculation
  - For foods without an on-label serving recommendation, it's a much more difficult analysis

# Safe Harbors

- Prop 65 safe harbors are set at extremely conservative levels
- Cancer safe harbor- **No Significant Risk Level:**
  - NSRL = The amount of a substance that will lead to a 1-in-100,000 increase in cancer risk, assuming lifetime exposure at that level
- Reproductive toxicity safe harbor- **Maximum Allowable Dose Level:**
  - MADL = amount of exposure that is less than 1/1000th of the level shown to have no observable reproductive effect



# Primary Substances of Concern

- Lead
  - MADL of 0.5 ug/day – most significant issue
  - NSRL of 15 ug/day
- Arsenic (inorganic arsenic compounds)
  - NSRL of 10 ug/day
  - Not a listed reproductive toxicant
- Arsenic (inorganic oxides)
  - No promulgated MADL
  - Not a listed carcinogen
- Cadmium and Mercury?

# Consent Judgment Reformulation Thresholds

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- The Prop 65 bounty hunter Consumer Advocacy Group (“CAG”) has been actively targeting the spice industry for several years now
- Some levels agreed to with Defendants:
  - Ground cinnamon 550 ppb of lead
  - Ground turmeric 375 ppb of lead
  - Ground ginger 720 ppb of lead

# Determine Your Compliance?

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- Test product from various lots to get a sense for heavy metal content over time
- Determine a conservative daily dose of the spice at issue, multiply it by your highest test result, and see how it compares to the safe harbor
- Use the ASTA tool for further information
  - Uses average daily consumption based on arithmetic mean
- Hire an attorney specializing in Prop 65 and compare to consent judgment reformulation standards

# Questions

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**Agriculture  
and Markets**

# Regulatory Policies for Heavy Metals in Spices - A New York Approach.

Jon Greenberg, Director  
Division of Food Safety and Inspection

## Regulatory Policies for Heavy Metals in Spices - A New York Approach

- Over the last decade, through its routine food surveillance program, the New York State Department of Agriculture and Markets (AGM) has seen a significant rise in the prevalence of heavy metal contamination of imported spices.
- However, no federal action limit for heavy metals in spices currently exists.
- In 2014, New York State created state action limits of 1 and 25 part per million (ppm), for Class 2 and 1 recalls for lead (Pb).

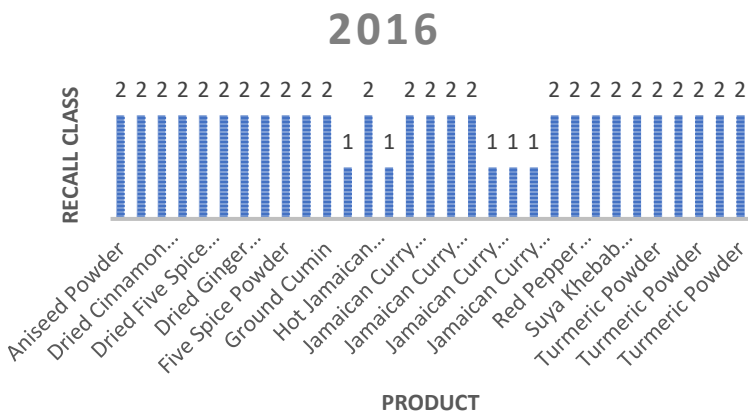
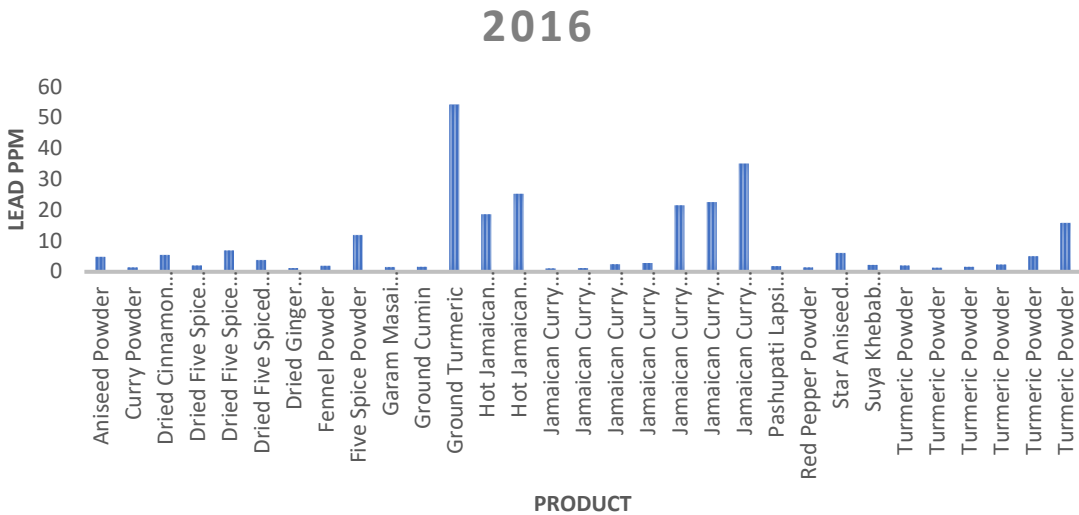
## Regulatory Policies for Heavy Metals in Spices - A New York Approach

- AGM has been sampling products for the presence of adulterants in imported spices for decades.
- Initially, testing for adulterants primarily focused on testing for unallowable dyes and allergens.
- In 2014, the AGM Food Laboratory (FL) analysts noticed an increase in the number of spices containing Pb-based dyes, such as Pb chromate, and cadmium (Cd) pigments, causing NYSAGM to shift its focus to testing and analyzing such samples for heavy metals.

Year 2016					Year 2016				
Product	Pb	Origin	Country of Origin	Recall Type	Product	Pb	Origin	Country of Origin	Recall Type
	concentration in ppm			(1 or 2)		concentration in ppm			(1 or 2)
Aniseed Powder	4.83	Imported	China	2	Jamaican Curry Powder	2.37	Domestic	Not applicable	2
Curry Powder	1.31	Unknown	Not listed	2	Jamaican Curry Powder	2.79	Domestic	Not applicable	2
Dried Cinnamon Powder	5.39	Imported	China	2	Jamaican Curry Powder	21.5	Domestic	Not applicable	1
Dried Five Spice Powder	1.95	Imported	China	2	Jamaican Curry Powder	22.6	Domestic	Not applicable	1
Dried Five Spice Powder	6.91	Imported	China	2	Jamaican Curry Powder	35	Domestic	Not applicable	1
Dried Five Spiced Powder	3.71	Imported	China	2	Pashupati Lapsi Powder	1.77	Imported	Nepal	2
Dried Ginger Powder	1.13	Imported	China	2	Red Pepper Powder	1.4	Imported	Taiwan	2
Fennel Powder	1.88	Imported	China	2	Star Aniseed Powder	6.06	Imported	China	2
Five Spice Powder	11.9	Imported	China	2	Suya Khebab Powder	2.16	Imported	Ghana	2
Garam Masai Powder	1.41	Imported	India	2	Turmeric Powder	2.03	Imported	Vietnam	2
Ground Cumin	1.57	Domestic	Not applicable	2	Turmeric Powder	1.25	Imported	Thailand	2
Ground Turmeric	54.11	Domestic	Not applicable	1	Turmeric Powder	1.56	Imported	Thailand	2
Hot Jamaican Curry Powder	18.6	Domestic	Not applicable	2	Turmeric Powder	2.3	Imported	Vietnam	2
Hot Jamaican Curry Powder	25.3	Unknown	Not listed	1	Turmeric Powder	5	Imported	Bangladesh	2
Jamaican Curry Powder	1.07	Domestic	Not applicable	2	Turmeric Powder	15.8	Unknown	Not listed	2
Jamaican Curry Powder	1.18	Domestic	Not applicable	2					

Average Class 2 Recall ppm: 4.13  
Average Class 1 Recall ppm: 31.70

Number Class 2 Recalls - 26  
Number Class 1 Recalls - 5





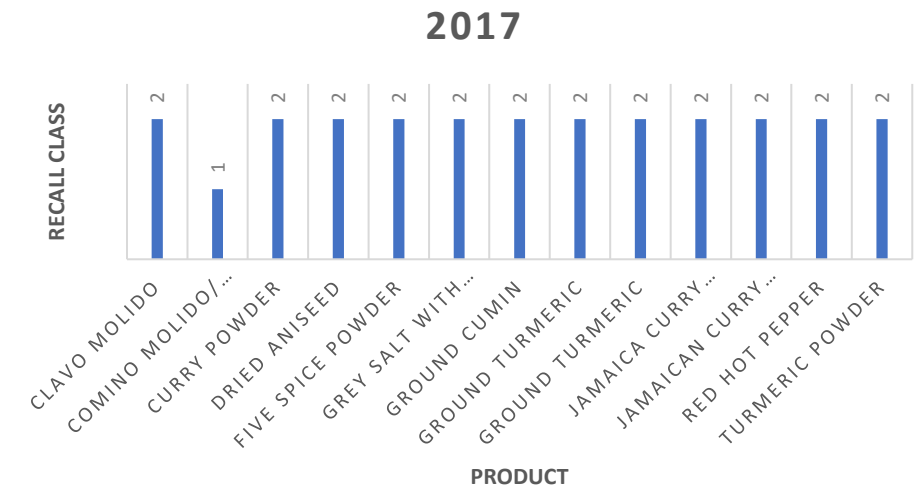
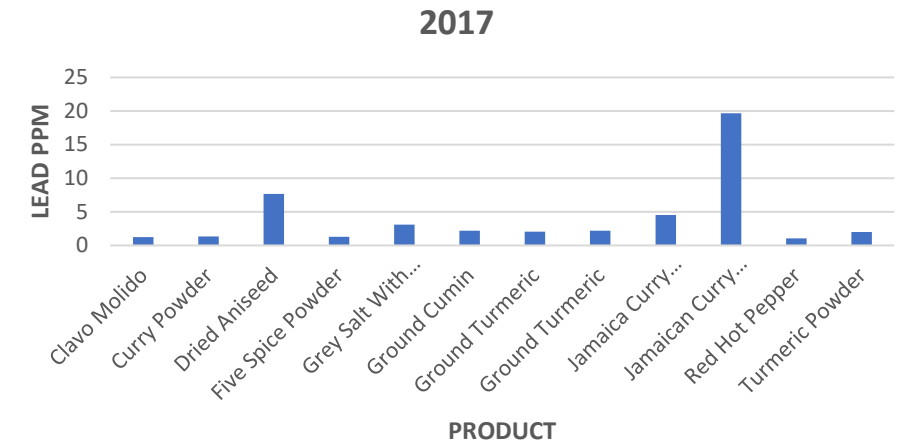
Year 2017				
Product	Pb	Origin	Country of Origin	Recall Type
	concentration in ppm			(1 or 2)
Clavo Molido	1.2	Unknown	Not listed	2
Comino Molido/ Ground Cumin	10902	Imported	India	1
Curry Powder	1.33	Unknown	Not listed	2
Dried Aniseed	7.67	Imported	China	2
Five Spice Powder	1.26	Imported	Taiwan	2
Grey Salt With Black Summer Truffles	3.09	Imported	Italy	2
Ground Cumin	2.2	Unknown	Not listed	2
Ground Turmeric	2.03	Domestic	Not applicable	2
Ground Turmeric	2.19	Imported	Not listed	2
Jamaica Curry Powder	4.49	Unknown	Not listed	2
Jamaican Curry Powder	19.7	Unknown	Not listed	2
Red Hot Pepper	1.02	Imported	Turkey	2
Turmeric Powder	2	Imported	Thailand	2

Average Class 2 Recall ppm: 4.02

Average Class 1 Recall ppm: 10902

Number Class 2 Recalls - 12

Number Class 1 Recalls - 1

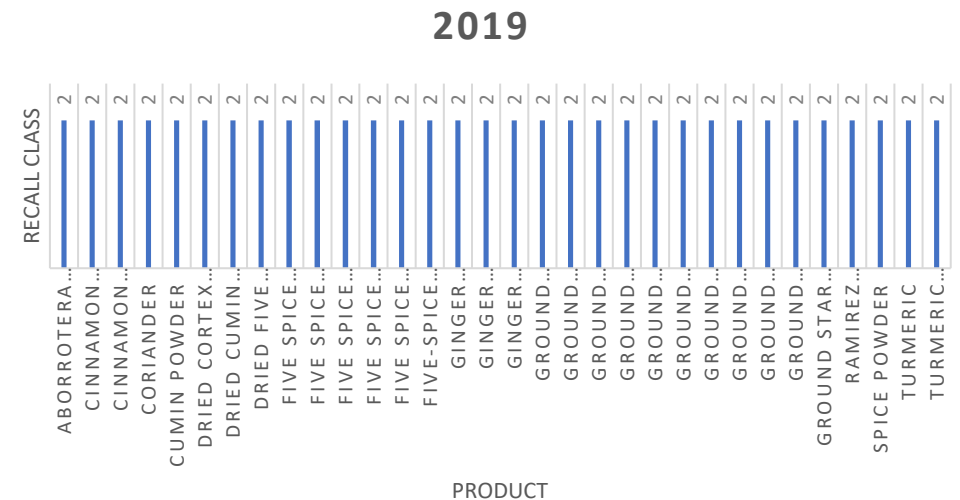
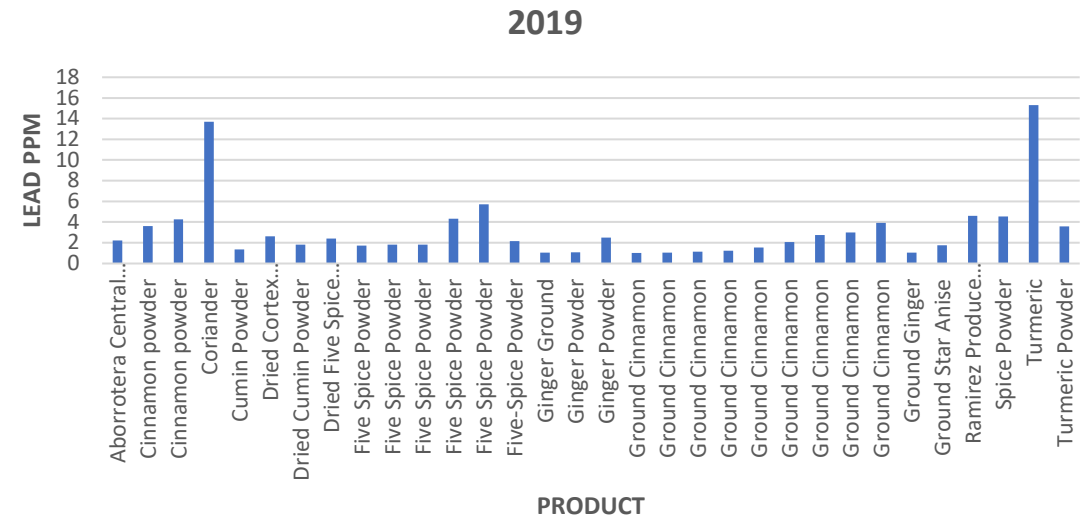




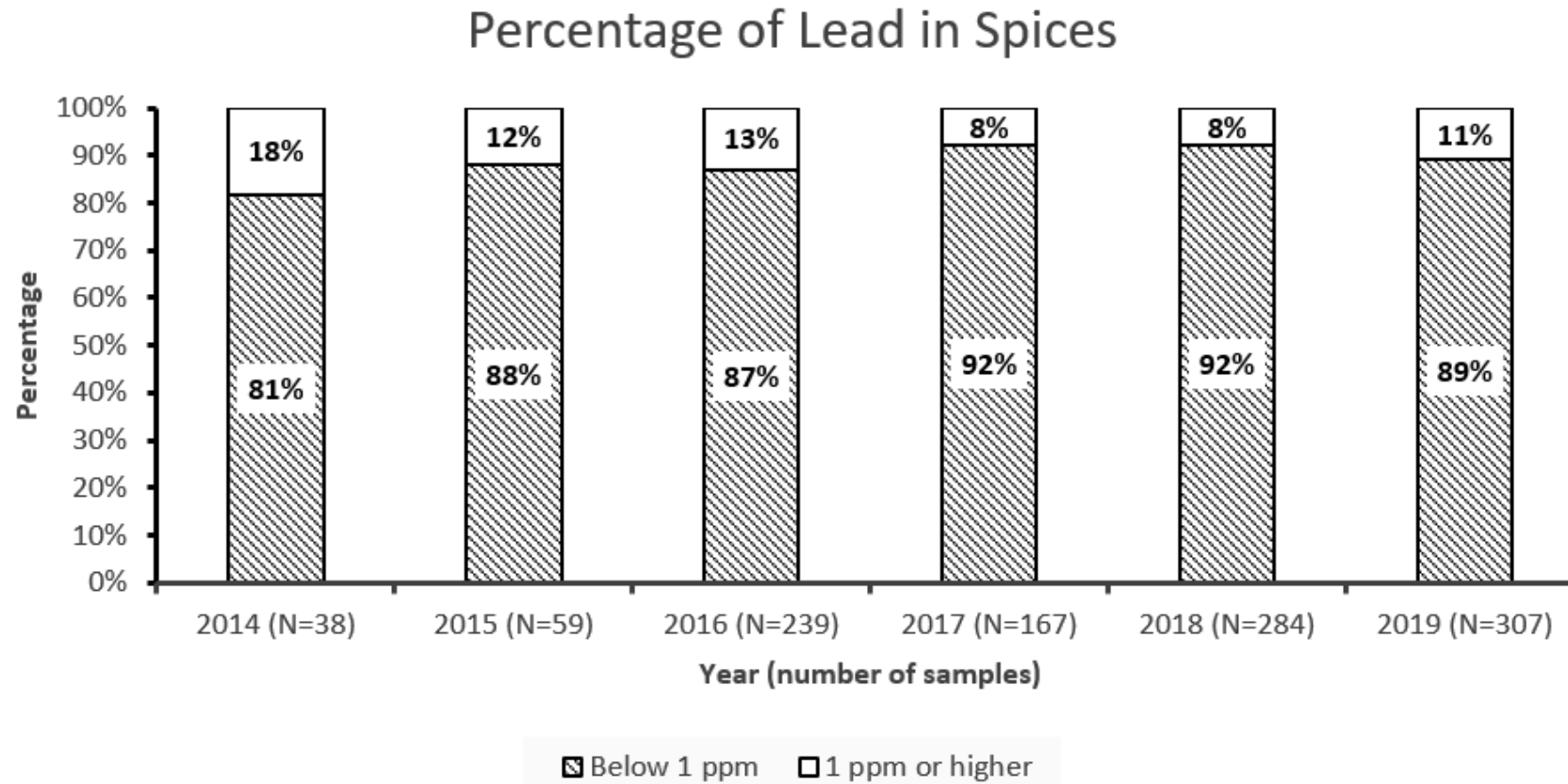
Year 2019 (Jan-June)				
Product	Pb	Origin	Country of Origin	Recall Type
	concentration in ppm			(1 or 2)
Cinnamon Powder	4.27	Domestic	Not applicable	2
Five Spice Powder	5.72	Imported	Hong Kong	2
Ginger Ground	1.03	Domestic	Not applicable	2
Ginger Powder	1.06	Domestic	Not applicable	2
Ginger Powder	2.48	Domestic	Not applicable	2
Ground Cinnamon	1.13	Imported	Indonesia	2
Ground Cinnamon	2.74	Unknown	Not listed	2
Ground Cinnamon	3.91	Unknown	Not listed	2
Ground Ginger	1.03	Unknown	Not listed	2
Ground Star Anise	1.74	Imported	China	2

Average Class 2 Recall ppm: 2.61

## Number Class 2 Recalls - 10



Percentage of lead (Pb) in spices found by the NYSAGM from 2014 to 2019 in two level ranges: 0-1 ppm and 1 ppm or higher.





## Regulatory Policies for Heavy Metals in Spices - A New York Approach

In 2018, NYSAGM began a Mutual Reliance Pilot Project with The Food and Drug Administration (FDA). NYSAGM resources are used to sample and analyze FDA regulated imported products at the retail level. When samples are determined to be violative and result in NYSAGM recall, this is communicated to the FDA to trigger, as appropriate, domestic import recalls (outside NY), domestic follow-up inspections, foreign inspections, imported bulleting surveillance, additions to an existent Import Alert, or a new one.

## Regulatory Policies for Heavy Metals in Spices - A New York Approach

Protecting New York's consumers is the State's top priority and effective implementation of its public health mission is vital.

In his State of the State Message in 2018, Governor Cuomo launched an initiative, whereby NYSAGM and the New York State Department of Health (NYSDOH) created a Center of Excellence on Food Research to further study heavy metals in spice. This collaborative effort charged NYSDOH with quantitatively evaluating the health effects of heavy metals in spices and developing health-based guidance values to address this adulteration. Based on the results of this study, NYSDAM will lower the state's recall action limits for heavy metals in spices and update its recall policy.

# Regulatory Policies for Heavy Metals in Spices - A New York Approach

According to the US Department of Agriculture (USDA), the US is the world's largest importer of more than 40 distinct spices from more than 50 countries. The increase in spice ingestion trends is partly due to:

- General enjoyment of food, while at the same time thought to be used to reduce fat and salt intake in the US diet (Peters et al., 2014, Anderson et al., 2015).
  - Others are adding spices to their daily routine because of their apparent natural anti-microbial and anti-inflammatory properties.
- In order to successfully implement the State's new recall policy and subsequent enforcement activities, NYSAGM will take a phased approach to educate its stakeholders.

# Regulatory Policies for Heavy Metals in Spices - A New York Approach

NYSAGM recognizes that it will take time for the industry to fully implement the new recall action limits. There is currently product that is acceptable by today's limits that is:

- In the retail stores
- In the blenders and packers possession
- Harvested

New areas of lower contamination may have to be found.

The new limits will be implemented within 18 months of the public announcement of the NYSAGM updated recall policy.



# Regulatory Policies for Heavy Metals in Spices - A New York Approach

During the implementation phase, NYSAGM intends to work with:

- Importers
- Wholesalers
- Retailers
- Manufacturers (spice manufacturers and those using spices as ingredients in their finished products), and any other relevant industry partners.

NYSAGM will engage in a comprehensive outreach and education strategy:

- Speaking at national and regional food safety conferences
- Hosting in-person meetings and
- Providing those affected by this change various forms of written communication to ensure they are aware of this change.

# Questions

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